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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/127,364 | 07/31/1998 | THEODORE A. YEDNOCK | 193-US-CIP2 | 1040 |

7590 12/11/2001

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| EXAMINER |
|---|
| LUKTON, DAVID |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | 18 |

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/127,364 | Yednock |
| **Examiner** | **Art Unit** |
| David Lukton | 1653 |

*-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Oct 3, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-10 and 24-36* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-10 and 24-36* are subject to restriction and/or election requirem

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Pursuant to the directives of paper No. paper No. 17 (filed 10/3/01), claims 24-36 have been added. Claims 1-10 and 24-36 are pending.

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A restriction is imposed; first however, the following subgenera are defined:

**G1**: within this subgenus, both of the following conditions are met:

(a) the assay system requires the presence of both an *alpha*-9 integrin and an *alpha*-9 integrin ligand; and

(b) the "activity" referred to in claim 24 is that of the propensity of the recited compounds to compete with an *alpha*-9 integrin ligand for binding to the *alpha*-9 integrin

**G2**: at least one of the following conditions is met:

(a) the assay system does not require the presence of an *alpha*-9 integrin

(b) the assay system does not require the presence of an *alpha*-9 integrin ligand

(c) the "activity" referred to in claim 24 can be anything that can be measured in a biological assay, as long as it does not require binding to an *alpha*-9 integrin.

**G3**: the compound that is administered to the subject (claim 31) is limited to those recited in claims 34-36.

**G4**: the compound used in the method of claim 31 can be whatever is permitted by the claims, provided that G3 is excluded.

*

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-10, drawn to compositions which contain *alpha*-9 integrin antagonists.

2. Claims 24-27, 29, 30, drawn to a method of conducting an assay which is limited to G1, and which measures binding between *alpha*-9 integrin and a cognate ligand.

3. Claims 24-27, 29, 30, drawn to a method of conducting an assay which is limited to G2, and which measures binding between *alpha*-9 integrin and a cognate ligand.

4. Claim 28, drawn to a method of measuring competition between VCAM-1 and a test compound for binding to an alpha-4/beta-1 integrin.

5. Claims 31-36, drawn to a method of treating an inflammatory condition, limited to G3.

6. Claims 31-36, drawn to a method of treating an inflammatory condition, limited to G4.

The claimed inventions are distinct.

Group I is drawn to compounds, whereas Groups 2-4 are drawn to an assay method, and Groups 5-6 are drawn to a method of treating an inflammatory condition.

In the event that applicants elect Group I, claims 24-36 will be withdrawn from consideration, and a new restriction will be imposed. That restriction is likely to be similar to, or identical to that previously imposed in this application.

Claims 24-27, 29, 30 have been bisected into two groups. Claim 24 is subject to more than one interpretation. Claim 24 recites the following (line 3):

"an assay system which measures an amount of alpha-9 integrin binding to an alpha-9

integrin ligand"

This could be interpreted to mean that any assay system is encompassed, even if there is no "amount" of binding, i.e., all that is required is an intent to determine whether there is an "amount" at all. For example, a practioner could rub two sticks together, and then state that the result of that experiment is that, as a consequence of rubbing the two sticks together, no binding between an alpha-9 integrin and a cognate ligand occurred. Thus, subgenus G1 has been created which requires that in the assay system, both the *alpha*-9 integrin and an *alpha*-9 integrin ligand must be present. Another issue raised by claim 24 is that of the "activity" which is exhibited by each of the nine compounds listed. Is the activity that of binding to the morphine receptor? Is the activity that of inducing a cell which bears a glucagon receptor to produce cyclic AMP? Is the activity that of lowering blood pressure? There are no limits set in claim 24. Accordingly, G1 also requires that the activity in question is directly and indisputably connected with *alpha*-9 integrin binding.

Applicants may, of course, elect Group 3, but if that decision is made, at least one additional restriction is likely. Accordingly, in the event that applicants elect Group 3, it is suggested that claim 24 be amended to make it clear what is required by the assay.

Claim 28 is also subject to interpretation. Claim 28 is not properly subgeneric to any of the preceding claims. For example, the term "inhibition of binding of alpha-4/beta-1" lacks antecedent basis. Moreover, none of claims 24-27 requires that one ever have possession of an alpha-4/beta-1 integrin. At the present time, claim 28 is regarded as distinct from

any of claims 24-27; however, applicants may amend claim 28 to make it clear that it is necessarily subgeneric to claim 24. If that is done, the restriction may be revised in applicants' favor.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

- In the event that applicants elect Group 3, the species to be elected are:

  (a) a specific integrin, (b) a specific "cognate ligand" of that integrin, and (c) a specific "activity" of the nine compounds listed in claim 24.

- In the event that applicants elect either of Groups 5 or 6, the species to be elected are:

  (a) a specific *alpha*-9 antagonist compound that is administered to the subject, and

  (b) a specific "inflammatory condition".

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

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As noted previously, this application is, at least potentially, an "aggregation vehicle" for other applications. In the event that applicants elect Group 1, it is suggested, but not yet required, that applicants indicate which of the applications that have been cited in the instant application they would like to have examined (e.g., S.N. 08/904,424).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600